

Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

TITLE III

OFFICIAL CONTROLS AND FINAL PROVISIONS

CHAPTER I

Official controls

Article 44

Procedure for approval

1 The competent authority shall approve establishments or plants only where an on site visit, prior to start-up of any activity, has demonstrated that they meet the relevant requirements laid down in accordance with Article 27.

2 The competent authority may grant conditional approval if it appears, from the on site visit, that the establishment or plant meets all the infrastructure and equipment requirements with a view to ensuring the application of the operational procedures in compliance with this Regulation. It shall grant full approval only if it appears, from another on site visit carried out within three months of granting conditional approval, that the establishment or plant meets the other requirements referred to in paragraph 1. If clear progress has been made, but the establishment or plant still does not meet all of these requirements, the competent authority may extend conditional approval. However, conditional approval shall not exceed a total of six months.

3 Operators shall ensure that an establishment or plant ceases to operate if the competent authority withdraws its approval or in the case of conditional approval fails to extend it or to grant full approval.

^{F1}Article 45

[^{F1}Official controls]

.....

Textual Amendments

F1 Deleted by [Regulation \(EU\) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations \(EC\) No 999/2001, \(EC\) No 396/2005, \(EC\) No 1069/2009, \(EC\) No 1107/2009, \(EU\) No 1151/2012, \(EU\) No 652/2014, \(EU\) 2016/429 and \(EU\) 2016/2031 of the European Parliament and of the Council, Council Regulations \(EC\) No 1/2005 and \(EC\) No 1099/2009 and Council](#)

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE III. (See end of Document for details)*

Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (Text with EEA relevance).

Article 46

Suspensions, withdrawals and prohibitions on operations

1 If the official controls and supervision carried out by the competent authority reveal that one or more of the requirements of this Regulation are not met, it shall take appropriate action.

The competent authority shall in particular, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health:

- a suspend approvals of establishments or plants approved pursuant to this Regulation, if:
 - (i) the conditions for approving or operating the establishment or plant are no longer fulfilled;
 - (ii) the operator can be expected to remedy the deficiencies within a reasonable period of time; and
 - (iii) the potential risks to public and animal health do not require action in accordance with point (b);
- b withdraw approvals of establishments or plants approved pursuant to this Regulation, if:
 - (i) the conditions for approving or operating the establishment or plant are no longer fulfilled; and
 - (ii) the operator cannot be expected to remedy the deficiencies within a reasonable period of time:
 - for reasons relating to the infrastructure of the establishment or plant,
 - for reasons relating to the personal capacity of the operator or the staff under his supervision, or
 - because of serious risks to public and animal health requiring major adjustments to the operation of the establishment or plant before the operator may apply for re-approval;
- c impose specific conditions on establishments or plants in order to rectify existing deficiencies.

2 The competent authority shall, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health, temporarily or permanently prohibit operators referred to in Articles 23(1) and (3) and Article 24(1) from carrying out operations under this Regulation, as appropriate, following receipt of information indicating:

- a that the requirements of [F²retained EU law] are not met; and
- b potential risks to public or animal health arising from such operations.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE III. (See end of Document for details)

Textual Amendments

- F2** Words in Regulation substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), **reg. 12(2)**

Article 47

Lists

1 [F3The appropriate authority] shall draw up a list of establishments, plants and operators which have been approved or registered in accordance with this Regulation within its [F4constituent nation].

It shall assign an official number to each approved or registered establishment, plant or operator, which identifies the establishment, plant or operator with respect to the nature of its activities.

[F5The appropriate authority] shall indicate, if applicable, an official number which has been assigned to the establishment, plant or operator under other [F2retained EU law].

F6
...

[F7The appropriate authority] shall keep up-to-date the lists of approved or registered establishments, plants and operators [F8in their constituent nation] and make them available to [F9the other appropriate authorities, the Department of Agriculture, Environment and Rural Affairs] and to the public.

2 [F10The appropriate authority may, by regulations, make such provision as the appropriate authority considers necessary or expedient to implement this Article, including provisions relating to]:

- a the format for the lists referred to in paragraph 1; and
- b the procedure for making the lists referred to in paragraph 1 available.

Textual Amendments

- F2** Words in Regulation substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), **reg. 12(2)**
- F3** Words in Art. 47(1) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **12(22)(a)(i)**
- F4** Words in Art. 47(1) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **12(22)(a)(ii)**
- F5** Words in Art. 47(1) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **12(22)(b)**
- F6** Words in Art. 47(1) omitted (E.W.S.) (31.12.2020) by virtue of [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **12(22)(c)**

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE III. (See end of Document for details)

- F7** Words in Art. 47(1) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **12(22)(d)(i)**
- F8** Words in Art. 47(1) inserted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **12(22)(d)(ii)**
- F9** Words in Art. 47(1) substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **12(22)(d)(iii)**
- F10** Words in Art. 47(2) substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019 \(S.I. 2019/588\)](#), regs. 1, **8(26)** (with reg. 12); 2020 c. 1, Sch. 5 para. 1(1)

^{FII}Article 48

Controls for dispatch to other Member States

Textual Amendments

- F11** Art. 48 omitted (E.W.S.) (31.12.2020) by virtue of [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **12(23)**

^{F1}^{F1}Article 49

Community controls in Member States

Textual Amendments

- F1** Deleted by [Regulation \(EU\) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations \(EC\) No 999/2001, \(EC\) No 396/2005, \(EC\) No 1069/2009, \(EC\) No 1107/2009, \(EU\) No 1151/2012, \(EU\) No 652/2014, \(EU\) 2016/429 and \(EU\) 2016/2031 of the European Parliament and of the Council, Council Regulations \(EC\) No 1/2005 and \(EC\) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations \(EC\) No 854/2004 and \(EC\) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC \(Official Controls Regulation\) \(Text with EEA relevance\).](#)

^{F1}Article 50

Application of Regulation (EC) No 882/2004 for the purposes of certain controls]

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE III. (See end of Document for details)

Textual Amendments

- F1** Deleted by Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (Text with EEA relevance).

CHAPTER II

Final provisions

^{F12}Article 51

National provisions

Textual Amendments

- F12** Art. 51 omitted (E.W.S.) (31.12.2020) by virtue of The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **12(23)**

^{F13}Article 51a

Exercise of the delegation

Textual Amendments

- F13** Art. 51a omitted (31.12.2020) by virtue of The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **12(23)**

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE III. (See end of Document for details)

F14 Article 52

Regulations

1 Regulations made by the Secretary of State or the Welsh Ministers under this Regulation are to be made by statutory instrument.

2 For regulations made under this Regulation by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010.

4 A statutory instrument containing regulations made by the Secretary of State under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

5 A statutory instrument containing regulations made by the Welsh Ministers under this Regulation is subject to annulment in pursuance of a resolution of the Welsh Parliament.

6 Regulations made by the Scottish Ministers under this Regulation are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

8. Regulations made under this Regulation may—

a contain consequential, incidental, supplementary, transitional or saving provision, including provision amending, repealing or revoking enactments (which has the meaning given by section 20(1) of the European Union (Withdrawal) Act 2018); and

b make different provision for different purposes.

9. Before making any regulations under this Regulation, the appropriate authority must consult—

a such bodies or persons as appear to the appropriate authority to be representative of the interests likely to be substantially affected by the regulations;

b such other bodies or persons as the appropriate authority may consider appropriate.]

Textual Amendments

F14 Art. 52 substituted (31.12.2020) by [The Animals \(Legislative Functions\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/588), regs. 1, **8(28)** (with reg. 12) (as amended by S.I. 2020/1463, regs. 1(2)(a), **6(5)(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F15 Article 53

Penalties

.....

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE III. (See end of Document for details)

Textual Amendments

- F15** Art. 53 omitted (E.W.S.) (31.12.2020) by virtue of [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **12(23)**

Article 54

Repeal

Regulation (EC) No 1774/2002 shall be repealed with effect from 4 March 2011.

References to Regulation (EC) No 1774/2002 shall be construed as references to this Regulation and shall be read in accordance with the correlation table laid down in the Annex.

Article 55

Transitional measure

Establishments, plants and users approved or registered in accordance with Regulation (EC) No 1774/2002 before 4 March 2011 shall be deemed to be approved or registered, as required, in accordance with this Regulation.

^{F16} Article 56

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union* .

It shall apply from 4 March 2011.

^{F17}]

Textual Amendments

- F16** Substituted by [Council Regulation \(EU\) No 1385/2013 of 17 December 2013 amending Council Regulations \(EC\) No 850/98 and \(EC\) No 1224/2009, and Regulations \(EC\) No 1069/2009, \(EU\) No 1379/2013 and \(EU\) No 1380/2013 of the European Parliament and of the Council, following the amendment of the status of Mayotte with regard to the European Union.](#)
- F17** Words in Art. 56 omitted (E.W.S.) (31.12.2020) by virtue of [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **12(24)**

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, TITLE III.